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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/016,767	10/30/2001	Edward M. Atkinson	226272003310	3324

25226 7590 12/16/2003  
MORRISON & FOERSTER LLP  
755 PAGE MILL RD  
PALO ALTO, CA 94304-1018

EXAMINER

HILL, MYRON G

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 12/16/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

10/016,767

**Applicant(s)**

ATKINSON ET AL.

**Examiner**

Myron G. Hill

**Art Unit**

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 13 September 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 8- 34, 50, 51, 53- 92, 118, 119, 159- 162 and 178- 194 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 8- 21, 50, 51, 53- 92, and 178- 194 is/are allowed.
- 6) ☒ Claim(s) 22- 34, 118, 119, and 159- 162 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All   b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)                      4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)                      5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_                      6) ☐ Other: \_\_\_\_\_

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### **DETAILED ACTION**

This office action is in response to Amendment C filed 13 September 2003.

Claims 8- 34, 50, 51, 53- 92, 118, 119, 159- 162 and 178- 192 are under consideration.

#### ***Drawings***

The Draftsman accepts the drawings filed 10/30/01.

#### ***Response to Amendment***

#### ***Rejections and Objections Withdrawn***

#### ***Claim Rejections - 35 USC § 102***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 8, 9, and 17- 20 were rejected under 35 U.S.C. 102(b) as being anticipated by O'Riordan (WO 97/08298).

Applicant's argument that the method as claimed is not anticipated by O'Riordan is found persuasive.

#### ***Claim Rejections - 35 USC § 103***

Claims 10- 12 and 13- 16 were rejected under 35 U.S.C. 103(a) as being unpatentable over O'Riordan (WO 97/08298).

Applicant's argument that the method as claimed is not taught by or obvious over O'Riordan is found persuasive.

Claims 21, 50, 51, 53- 92 were rejected under 35 U.S.C. 103(a) as being unpatentable over O'Riordan (WO 97/08298) and Graham (*J. Gen. Virol.* 1987, vol. 68 pages 937- 940) and/or further in view of Shenk (US Pat 5,346,146)

Applicant's argument that the method as claimed is not taught by or obvious over O'Riordan and Graham is found persuasive.

### **Rejections Maintained**

#### ***Double Patenting***

Claims 22- 34, 118, 119, and 159- 162 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 126 and 159- 162 of allowed U.S. Patent Application No. 09/526,333. Although the conflicting claims are not identical, the claims are not patentably distinct from each other because AAV is purified from the supernatant without a lysis step using anion and cation chromatography.

Applicants state they will address this issue after determination of allowable claims.

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Applicant's arguments have been considered and not found persuasive.

The rejection is maintained but allowable subject matter is indicated below.

### **New Rejections**

#### ***Double Patenting***

Claim 118 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 117 and 118 of copending Application No. 10/020482. Both sets of claims are drawn to a method of generating a population of rAAV by culturing the producer cells under sub-lethal stress and purifying the rAAV by means of chromatography and filtration. Because of the open language of the instant claim, the claims encompass the copending claim 118. The limitations of cancelled claim 117 in this application have been included in claim 118 to make the instant claim 118 independent and not identical in the context of statutory double patenting.

This is a provisional obviousness-type double patenting rejection.

#### ***Allowable Subject Matter***

Claims 8- 34, 50, 51, 53- 92, 118, 119, 159- 162 and 178- 194 are allowed.

The claims are free of the prior art except as indicated in the double patenting rejection.

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***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Myron G. Hill whose telephone number is 703-308-4521. The examiner can normally be reached on 9am-6pm Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4027. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9306 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Myron G. Hill  
Patent Examiner  
December 12, 2003

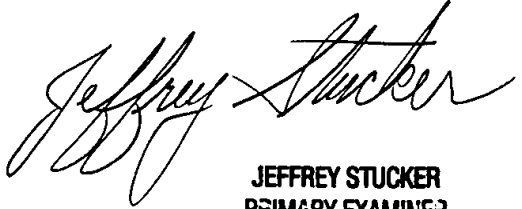
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Myron G. Hill  
Patent Examiner  
December 9, 2003



JEFFREY STUCKER  
PRIMARY EXAMINER